MAY 2 0 2014

510(k) Summary

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the ASAP OTC™ Wound Dressing Gel is provided below.

Device Common Name:	Wound Dressing
Device Proprietary Name:	ASAP OTC™ Wound Dressing Gel
Submitter:	ABL Medical, LLC 705 E 50 S American Fork, UT 84003
Contact:	Calley Herzog Consultant Biologics Consulting Group, Inc. 400 N. Washington St., Suite 100 Email: cherzog@bcg-usa.com Phone: 720-883-3633 Fax: 703-548-7457
Date Prepared:	May 16, 2014
Classification Regulation:	Unclassified
Panel:	General & Plastic Surgery
Product Code:	FRO
Predicate Device:	K082333, ASAP Wound Dressing Gel

Indication for Use:

ASAP OTC™ Wound Dressing Gel is indicated for the topical management of minor cuts, lacerations, abrasions, 1st and 2nd degree burns, and skin irritations.

Device Description:

ASAP OTC™ Wound Dressing Gel is a water based gel wound dressing that contains silver hydrosol that may inhibit the growth of microorganisms within the dressing.

The high moisture content gel contains a base matrix composed of hydrophilic and buffering compounds and contains silver from American Biotech Labs' proprietary silver hydrosol suspension. ASAP OTC™ Wound Dressing Gel is supplied in a multi-dose gel pump and a tube (collapsible, low-density polyethylene lined metal tube, sealed on one end and fitted with a pop-open screw cap on the other end).

Performance Data:

The device was evaluated with biocompatibility testing (ISO 10993) and was found to be acceptable. The gel contains silver hydrosol that may inhibit the growth of microorganisms within the dressing. Antimicrobial effectiveness was established through testing in accordance

with USP <51> and was shown to inhibit the growth of microorganisms such as: *Staphylococcus aureus, Pseudomonas aeruginosa, Escherichia coli*, MRSA and VRE, as well as fungi such as *Candida albicans* and *aspergillus niger.*

Substantial Equivalence Summary:

The composition of ASAP OTC™ Wound Dressing Gel is similar to that of the ASAP Wound Dressing Gel cleared in K082333. The only differences between the subject device and the predicate device are that 1) the subject device contains 24ppm silver hydrosol and the predicate device contains 32ppm silver hydrosol and 2) the subject device does not contain propylene glycol.

Table 1: Device Comparison Table

	Proposed Device	**Predicate Device**
510(k) Number	TBD	K082333
Submitter	ABL Medical, LLC	American Biotech Labs (Note: 510(k) ownership has been transferred to ABL Medical LLC)
Classification Regulation	Unclassified	Unclassified
Product Code	FRO	FRO
Indication	ASAP OTC™ Wound Dressing Gel is indicated for the topical management of minor cuts, lacerations, abrasions, 1st and 2nd degree burns, and skin irritations.	For the topical management of minor cuts, lacerations, abrasions, 1st and 2nd degree burns, and skin irritations. (Over-the-Counter)
Packaging	Multi-dose gel pump or a tube (collapsible, low-density polyethylene lined metal tube, sealed on one end and fitted with a pop-open screw cap on the other end)	Multi-dose gel pump or a tube (collapsible, low-density polyethylene lined metal tube, sealed on one end and fitted with a pop-open screw cap on the other end)
Sterilized	Not provided sterile	Not provided sterile
Shelf Life	No shelf life claimed	No shelf life claimed
Ingredients		
Active & Diluent	24 ppm ASAP Solution – 98.42%	32 ppm ASAP Solution – 91%
Thickening Agent	Carbopol ETD 2020 – 0.58%	Carbopol ETD 2020 – 0.58%
Buffering Agent, Penetrating Agent	Triethanolamine (TEA) – 1%	Triethanolamine (TEA) – 1%
Humectant	-	Propylene Glycol – 7%

	Proposed Device	Predicate Device
Specifications		
Appearance	Clear to golden yellow translucent gel	Clear to golden yellow translucent gel
Odor	Odorless	Odorless
Specific Gravity	1.01	1.02
Flowability	At 45° & 90° - more than 5 min. to travel 1 inch from the origin	At 45° & 90° - more than 5 min. to travel 1 inch from the origin
Feel/Tackiness	1 - smooth	1 - smooth
Viscosity RT 30°	25,000 - 60,000	25,000 - 60,000
PH	6.5 to 8.0	6.5 to 8.0
Light Exposure	No further discoloration	No further discoloration
Compatibility	No discoloration of product / reaction with containers	No discoloration of product / reaction with containers
Moisture Donation	Greater than 5%	Greater than 5%
Moisture Uptake	Greater than 5%	Greater than 5%

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 20, 2014

ABL Medical, LLC
% Ms. Calley Herzog
Biologics Consulting Group Incorporated
400 North Washington Street, Suite 100
Alexandria, Virginia 22314

Re: K140483
Trade/Device Name: ASAP OTC™ Wound Dressing Gel
Regulatory Class: Unclassified
Product Code: FRO
Dated: April 22, 2014
Received: April 24, 2014

Dear Ms. Herzog:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K140483

Device Name
ASAP OTC™ Wound Dressing Gel

Indications for Use *(Describe)*
ASAP OTC™ Wound Dressing Gel is indicated for the topical management of minor cuts, lacerations, abrasions, 1st and 2nd degree burns, and skin irritations.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Jiyoung Dang -S